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Award Number: DAMD17-01-1-0565

TITLE: Defining Decision Support for Women With Recurrent Breast Cancer

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REPORT DATE: October 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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20030312 148

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 2002	3. REPORT TYPE AND DATES COVERED Annual (10 Sep 01 - 9 Sep 02)	
4. TITLE AND SUBTITLE Defining Decision Support for Women with Recurrent Breast Cancer			5. FUNDING NUMBERS DAMD17-01-1-0565	
6. AUTHOR(S) Penny F. Pierce, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Michigan Ann Arbor, Michigan 48109-1274 E-Mail: pfpierce@umich.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES Report contains color				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) <p><u>Purpose:</u> The intention of this study is to close the gaps in our knowledge regarding the decision-making experiences, challenges, and frustrations of women when breast cancer recurs. Therefore, the specific aims of this project are to: (1) provide a robust description of decision making processes of women faced with recurrent disease, (2) to describe preferences and values instrumental in the selection of treatment options (e.g., clinical trials, alternative therapies, adjuvant therapies, or no treatment), (3) to describe the manner in which previous treatment decision making experiences are, or are not influential, and lastly, (4) to describe the appraisals of decision processes and outcomes to identify those factors that contribute to, or impede, quality decision making.</p> <p><u>Scope:</u> Approximately 50 women recently diagnosed with recurrent disease will be recruited to participate in a semi-structured qualitative interview to describe her decision making experiences including her values and preferences regarding treatment. <u>Major Findings</u> : A Post-Award Change Approval was granted to modify the performance period to 10 Sep 2001 to 9 Oct 2003 due to extenuating circumstances surrounding the events of September 11, 2001. The project was initiated in September 2002 and is on schedule at this time.</p>				
14. SUBJECT TERMS recurrent breast cancer, decision making, psychological stress, decision outcomes			15. NUMBER OF PAGES 17	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

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INTRODUCTION

The intention of this study is to close the gaps in our knowledge regarding the decision-making experiences, challenges, and frustrations of women when breast cancer recurs. Therefore, the specific aims of this project are to: (1) provide a robust description of decision making processes of women faced with recurrent disease to generate hypotheses for future testing, and ultimately, for the design of prescriptive decision support interventions, (2) to describe preferences and values instrumental in the selection of treatment options (e.g., clinical trials, alternative therapies, adjuvant therapies, or no treatment), (3) to describe the manner in which previous treatment decision making experiences are, or are not influential, and lastly, (4) to describe the appraisals of decision processes and outcomes to identify those factors that contribute to, or impede, quality decision making. The proposed qualitative methodology uses a theoretical sampling of approximately 50 women newly diagnosed with recurrent disease to participate in a semi-structured interview designed to capture this complex and threatening real-world decision making experience. The ultimate objective of this preliminary descriptive work is to support the design of decision support interventions to enhance quality decision making in this vulnerable population.

BODY

This project has been granted a no-cost time extension setting a new start date of September 2002, due to the circumstances outlined in the request. Therefore, the project has just begun so there are no findings yet to report. As the Statement of Work prescribes, the tasks to be accomplished to initiate the project have been accomplished on schedule. Specifically, the proposal has been approved by the IRB at the Medical School at the University of Michigan and the protocol is now under consideration by the Protocol Review Committee of the Comprehensive Cancer Center. Data collection efforts between the Ann Arbor site and a community-based setting at St. Joseph's Mercy Hospital in Pontiac, Michigan, are staggered to allow for preparation of the second site and for the interviewers to gain experience. The additional site at St. Joseph's Mercy Hospital in Pontiac, Michigan, is included to provide a community-based sample and also to increase the attainment of an adequate sample size within the time constraints of this project. It is anticipated that we will be able to reach the goal of approximately 50 women with recurrent disease on or before August 2003.

Recruitment and hiring of a qualified team has been completed. The staff includes two experienced research assistants (RA) to recruit and interview subjects, to assist with data analysis, and to participate in dissemination of the findings through publications and presentations. An extensive interviewer training program was developed for this project and both RAs have undergone this training in preparation for approaching potentially distressed women to recruit them into the project. In addition, the training protocol provides guidance and feedback on conducting a non-threatening interview and introduces measures to insure quality data are obtained through use of the semi-structured interview instrument. Interviewers are instructed in ways to use probes, reflection, and other techniques to help subjects thoroughly cover the pertinent topics. Such training enhances the quality of interview data and minimizes the risk of psychological distress when asking questions regarding a potentially life threatening illness.

A Statement of Work was not included in the original proposal for this Concept Award so one has been developed to articulate the proposed tasks to be accomplished during the funding period.

STATEMENT OF WORK

[illegible]

KEY RESEARCH ACCOMPLISHMENTS

None at this time.

REPORTABLE OUTCOMES

None at this time.

CONCLUSIONS

None at this time.

APPENDICES

APPENDIX A Recruitment Brochure

APPENDIX B Survey Instrument

APPENDIX C Interview Schedule

APPENDIX A

Recruitment Brochure

Breast Care Choices...

Are sometimes difficult, frightening, overwhelming, and challenging to patients and their families.

Health care professionals do not always know the needs of women facing decisions for recurrent breast cancer treatment and care.

Expressing your needs, preferences, and values is an important part of making quality decisions.

Answers to these important questions only come from sharing decision experiences in a way that helps improve care and support.

Deciding how one lives is an important determinant of one's quality of life.

Decision Making Research Program

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Principal Investigator

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This project is supported by a grant from the
U.S. Army Breast Cancer Research Program
(BC996510;DAMD17-01-1-0565)

Defining Decision Support for Women with Recurrent Breast Cancer

**The University of Michigan
School of Nursing**

*A Program of
Research
Dedicated to
Understanding the
Breast Cancer
Decision Making
Experiences of
Women and Their
Families*

Cancer Care Choices

When you have cancer, you and your loved ones are faced with many decisions about issues that are probably new and unfamiliar to you. Sometimes people find these decisions to be troublesome because they are not feeling well, they are distressed about the diagnosis, or they simply don't know how to go about making such choices.

The University of Michigan
School of Nursing

is currently conducting a project that is intended to better understand the decision making experiences of women who are facing recurrent breast cancer treatment. In this project we will be trying to learn more about this important decision making experience, including the values and preferences of women and their families regarding cancer treatment and how their wishes are communicated to those who care for

Cancer Care Choices

If you are currently facing a second breast cancer treatment decision, we invite you to consider joining this project.

First, let us tell you what your participation would involve:

☞ Completion of a 16-item questionnaire and demographic information.

☞ One interview lasting approximately an hour where you would be asked to share your experiences with making breast cancer treatment decisions.

☞ The interview will be scheduled at a place and time that is most comfortable for you, including your home, should you desire.

Your participation is completely confidential and private.

Cancer Care Choices

The information provided by women like yourself will guide the development of future programs. Such programs will be designed to assist and support women and their families as they confront the many decisions involved in breast cancer treatment and care.

a

If you would like more information about the project, please call The Decision Making Research Program at the University of Michigan School of Nursing and speak to the Project Coordinator, Ms. Minnie Bluhm, at (734) 763-2068.

APPENDIX B

Survey Instrument

Defining Decision Support
For Women With Recurrent Breast Cancer

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This project is funded by a grant from the U.S. Army Breast Cancer Research Program (BC996510; DAMD17-01-1-0565)

DEMOGRAPHIC AND BACKGROUND INFORMATION

- Circle the appropriate number**

College/Yrs. of School

13 14 15 16 17+

- Circle the appropriate number**

5. Which of the following possibilities best describes your **present** marital status?

1. Never Married
2. Living with a partner
3. Married
4. Geographically separated due to conflicting military assignments
5. Separated (Breakdown of marriage)
6. Divorced (Due to conflicting military commitments)
7. Divorced (Breakdown of marriage)
8. Widowed

6. Are you currently living with your husband or with a partner?

1. Yes 5. No

The following are questions about your ethnic or racial background:

7. How would you describe your ethnic or racial background?

Please circle all that apply

- 1. White
- 2. Black/African American
- 3. American Indian, Eskimo or Aleut
- 4. Asian or Pacific Islander
- 5. Other, specify _____

8. Are you of Hispanic descent?

1. Yes 5. No

9. What is your current employment ?

- 1. Full time
- 2. Part time
- 3. Unemployed
- 4. Student

The following are questions about your history of breast cancer

10. When were you first diagnosed with breast cancer?

11. What was the type of breast cancer that was diagnosed at that time?

12. What treatment did you select at that time?

MICHIGAN ASSESSMENT OF DECISION STYLE
(Pierce, 1995)

Following are a few statements that describe typical decision making behavior of people considering medical treatments. Thinking of the decision you are about to make, circle the number on the scale that most closely resembles the way you are thinking about the decision you are about to make.

	1 No, definitely not	2	3 Neither yes or no	4	5 Yes, definitely
1. I would make a quick decision once I was told what my options were.	1	2	3	4	5
2. I would follow the recommendations of my physician	1	2	3	4	5
3. I would agree to the option that seemed the most reasonable to me at the time.	1	2	3	4	5
4. I would develop a plan for gathering further information	1	2	3	4	5
5. I would read magazines and articles about different treatments.	1	2	3	4	5
6. I would read scientific articles about the treatments that were being offered to me.	1	2	3	4	5
7. I would spend as much time as I could gathering information.	1	2	3	4	5
8. I would prefer to seek advice from specialists.	1	2	3	4	5
9. I would ask about the risks involved with each treatment alternative.	1	2	3	4	5
10. I would carefully consider the risks of each option as I was making a choice.	1	2	3	4	5
11. I would want to know the possible outcomes of each alternative that was being offered to me.	1	2	3	4	5
12. I would ask a lot of questions concerning the treatment options.	1	2	3	4	5
13. I would want someone else to make the decision for me.	1	2	3	4	5
14. I prefer, in situations like this, that someone else tells me what to do.	1	2	3	4	5
15. I prefer not knowing the possibility that unexpected things could happen to me.	1	2	3	4	5
16. I believe that what will happen, will happen and there is little I can do to change things.	1	2	3	4	5

APPENDIX C

Interview Schedule

Defining Decision Support for Women with Recurrent Breast Cancer

INTERVIEW SCHEDULE

INTRODUCTION

Hello Ms./Mrs/Dr _____.

My name is _____ and I am from the University of Michigan School of Nursing. We are conducting a research project that is intended to help us better understand how women like yourself make decisions for breast cancer when they are faced with the diagnosis a second time. In this study, we are trying to learn more about how women's experiences of making these choices, in what ways it might be different or similar to the first diagnosis, and how their values and preferences get communicated to those who care for them. If you would be interested in participating in the study, I would be happy to review the informed consent procedure with you at this time.

If no → Thank the patient for her time

If yes → Review the Informed Consent document, obtain a signature, and provide a copy to the subject

Set a date and time for the interview if the current setting is not appropriate

I would like to ask you to tell me about how you made the decision regarding treatment the first time you were diagnosed with breast cancer and how you are going about making a decision regarding treatment at this time. We can take a break when you wish or end the interview whenever you want to. Just let me know, at any time, if you would like to stop. If I ask a question you prefer not to answer, that's fine. You can just say "pass," and we'll move on.

Do you have any questions for me at this time?

OK then, we can begin if you are ready.

Can you tell me about the first time you were diagnosed; when that was and how you remember making the decision.

[Interviewer: allow the subject to complete her story in her own words at her own pace. Use the following probes only if she has not addressed the issue]

Probe → Do you remember the kinds of things that were important to you at the time you were making that decision?

Probe → Did you find that making the decision was difficult? If so, what made it difficult for you?

Probe → Who or what helped you make the decision?

As time has passed, what do you think now about the decision you made?

Probe → What are you most pleased/satisfied with about that decision?

Probe → Is there anything about how you went about making that decision that, on reflection, you would like to change now?

Probe → What “words of wisdom” would you pass along to other women who may find themselves in the same situation?

Probe → Was there anything that health professionals did to help you make your decision at that time?

Let's move forward to where we are today...

What is your reaction to facing this decision once more?

Probe → In what ways was this decision different from the first time?

Probe → Did you find that your experience from the first time helped or hindered you in making this decision? In what ways?

Probe → What did you learn about making decisions at that time that is helpful to you now?

Probe → What suggestions do you have for health professionals that might be helpful to them as they counsel and support patients in making treatment decisions such as the one you are facing?

Is there any part of your experience that we did not talk about that you would like to share at this time?

Do you have any last questions for me?

Thank you for taking the time to share your experience with me.

[Give the subject the envelope containing the gift certificate of her choice]